

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| B. Braun Melsungen AG, et al., | : | |
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| Plaintiffs, | : | |
| | : | |
| v. | : | C.A. No. 09-347-JJF-LPS |
| | : | |
| Terumo Medical Corporation, et al., | : | |
| | : | |
| Defendants. | : | |

REPORT AND RECOMMENDATION
REGARDING CLAIM CONSTRUCTION

This action was filed by Plaintiffs B. Braun Melsungen AG & B. Braun Medical Inc. (collectively, “Braun”) against Defendants Terumo Medical Corporation and Terumo Corporation (collectively, “Terumo”) on May 13, 2009, alleging infringement of U.S. Patent No. 7,264,613 (“the ‘613 patent”). (D.I. 1) The case has been referred to me by Judge Farnan for certain purposes, including to make recommendations as to the proper construction of disputed claim terms. (D.I. 15; D.I. 110)

BACKGROUND

A. Procedure

Briefing on claim construction was completed in January 2010. (D.I. 71; D.I. 74; D.I. 97; D.I. 99) I held a *Markman* claim construction hearing on February 9, 2010. (*See* D.I. 126, Transcript of February 9, 2010 *Markman* hearing (hereinafter “Tr.”).) In addition, post-hearing

submissions – invited and uninvited – were filed as late as March 16, 2010.¹ (D.I. 127; D.I. 140; D.I. 155; D.I. 156; D.I. 157; D.I. 160) The parties have addressed eight claim terms, seven of which are disputed.²

B. The Patent-In-Suit – ‘613 Patent

The ‘613 patent, entitled “Spring Clip Safety IV Catheter,” was granted by the U.S. Patent and Trademark Office (“PTO”) on September 4, 2007. (D.I. 75 Ex. A (hereinafter “‘613 patent”)) The ‘613 patent contains 35 claims; the disputed terms appear in independent claims 1, 9, and 20, as well as in various dependent claims. (*Id.*) According to Braun, the 613 patent is one of several Braun patents that covers Braun’s Introcan Safety® IV Catheter. (D.I. 74 at 1)

In Braun’s words:

The ‘613 Patent relates to the field of peripheral intravenous I.V. catheters, and in particular, to the field of safety I.V. catheters. A peripheral I.V. catheter is a type of medical device used to place a catheter in a vein of a patient’s arm (or less commonly other peripheral parts of the body). A catheter is a slender tube that, once entered into the patient’s vein, permits fluid communication with the vein to withdraw blood or administer medicinal fluids. Intravenous catheters are typically sold and packaged with needles as a single device. The catheter typically has (1) a catheter tube which has a tip at one end to enter the vein and, (2) a catheter hub attached to the other end of the tube, which allows a fluid connection to a syringe or an I.V. line. The needle typically has (1) an elongated metal needle with a sharp tip on one end, and (2) a needle hub for holding the needle at the other end. Typically, the catheter and needle are packaged as two components of a single device, where the needle extends through the catheter tube with its tip extending out of the tip of the catheter and the catheter hub abuts the front of the needle hub. . . .

¹*See infra* n.11.

²The parties agree that the eighth term, “clip stopping section,” should be construed to mean “a section of the needle for stopping the clip, including but not limited to a crimp.” (D.I. 71 at 30; D.I. 74 at 28) I recommend that the Court adopt this agreed-upon construction.

To place the catheter into a vein, the healthcare worker uses the needle tip to pierce the patient's skin and guide the needle and surrounding catheter tip into the patient's vein. The catheter is fed into the vein while the needle is withdrawn by pulling the needle back out of the catheter. In this manner, the catheter is left in the vein and the needle can be disposed of. . . .

(D.I. 74 at 4-5)

The "Field of the Invention" of the '613 patent recites: "This invention relates generally to intravenous (IV) catheters, and, in particular, to a safety IV catheter in which the needle tip is automatically covered after needle withdrawal to prevent the healthcare worker from making accidental contact with the needle tip." ('613 patent, col. 1 lines 18-22)

C. Disputed Terms

Examples of the disputed claim terms are shown below, with emphasis added:

1. An IV catheter assembly comprising:
 - a first hub comprising an exterior surface and an interior surface defining an interior cavity;
 - a needle defining a needle shaft comprising a first dimension extending distally away from the first hub comprising a tip and a clip stopping section comprising a second different dimension positioned proximally of the tip;
 - a second hub comprising an exterior surface and an interior surface defining an interior cavity;
 - a catheter tube extending distally away from the second hub defining a lumen adopted to surround, at least in part, the needle shaft in the clip stopping section but not the tip;
 - a tip protector comprising a **proximal wall**, which comprises a proximally facing wall surface, a distally facing wall surface, and a continuous perimeter defining an opening, and two resilient **arms of different lengths extending distally** of the **proximal wall** each comprising a radially extending member at an end thereof; the tip protector is moveable with the first hub and relative to the second

hub in moving from a ready position to a protective position and the two resilient **arms** being biased radially when in the ready position;

and

wherein when the tip protector is in the protective position, by moving the first hub and the second hub relative to one another and causing the protective clip to move with the first hub relative to the second hub, the two resilient **arms** are no longer biased and move radially inwardly, the clip stopping section blocks the tip protector from further distal movement along the needle shaft, the two radially extending members block the tip, and the tip protector, including the **proximal wall**, remains with the needle.

8. The IV catheter assembly of claim 1, wherein the clip stopping section comprises a **crimp**.
9. An IV catheter apparatus comprising a first hub comprising a catheter tube extending distally thereof, a second hub comprising a needle having a needle axis and a needle tip extending distally of the second hub and extending through the first hub and the catheter tube with the needle tip extending beyond the catheter tube;

a clip cavity defined by an interior surface of the first hub;

a **needle protector clip** positioned in the clip cavity and having a ready to use position, in which the **needle protector clip** is positioned proximally of the needle tip, and a protective position, in which the **needle protector clip** blocks the needle tip; and

wherein the **needle protector clip** comprises a **proximal wall**, which comprises a proximally facing wall surface, a distally facing wall surface, and an opening, and two **arms** that **intersect** one another and **extend distally of** the **proximal wall** in the ready to use position.

17. The IV catheter apparatus of claim 9, further comprising a **crimp** located proximally of the needle tip.
20. An IV catheter assembly comprising:

a first hub comprising an exterior surface, an interior surface defining an interior cavity, and a distal end;

a catheter tube extending distally away from the first hub defining a lumen;

a second hub comprising an exterior surface and an interior surface defining an interior cavity;

a needle defining a needle shaft, having a side, extending distally away from the second hub and extending through the first hub and the lumen of the catheter tube when in a ready to use position, the needle having a needle tip at a distal end thereof;

a tip protector, which is positioned distally of the second hub, contacts an interior surface of the first hub, and is positioned inside and surrounded by the first hub, comprising a ***proximal wall***, which comprises a proximally facing wall surface, a distally facing wall surface, a ***proximal wall*** width, and a continuous perimeter defining an opening, and at least one ***arm*** attached to and ***extending distally of the proximal wall***; the at least one ***arm*** comprising a radially extending wall, which is positioned at an angle to the at least one ***arm*** and comprises a portion at a distal end abutting the side of the needle shaft when in the ready to use position; and

wherein the at least one ***arm*** comprises an ***arm*** section comprising an ***arm*** width of smaller width dimension than the ***proximal wall*** width.

28. The IV catheter assembly of claim 20, further comprising a needle ***crimp*** for engaging the opening when in the protective position.”

(‘613 patent, col. 15 lines 13-48, 62-67; *id.* col. 16 lines 1-13, 33-34, 41-67; *id.* col. 17 lines 18-20)

LEGAL STANDARDS

“It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotation marks omitted). Construing the claims of a patent presents a question of law. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977-78 (Fed. Cir.

1995), *aff'd*, 517 U.S. 370, 388-90 (1996). “[T]here is no magic formula or catechism for conducting claim construction.” *Phillips*, 415 F.3d at 1324. Instead, the court is free to attach the appropriate weight to appropriate sources “in light of the statutes and policies that inform patent law.” *Id.*

“[T]he words of a claim are generally given their ordinary and customary meaning . . . [which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” *Id.* at 1312-13 (internal citations and quotation marks omitted). “[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent.” *Id.* at 1321 (internal quotation marks omitted). The patent specification “is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.” *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

While “the claims themselves provide substantial guidance as to the meaning of particular claim terms,” the context of the surrounding words of the claim also must be considered. *Phillips*, 415 F.3d at 1314. Furthermore, “[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment . . . [b]ecause claim terms are normally used consistently throughout the patent . . .” *Id.* (internal citation omitted).

It is likewise true that “[d]ifferences among claims can also be a useful guide For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim.” *Id.* at 1314-15 (internal citation omitted). This “presumption is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one

party is urging that the limitation in the dependent claim should be read into the independent claim.” *SunRace Roots Enter. Co., Ltd. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003).

It is also possible that “the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor’s lexicography governs.” *Phillips*, 415 F.3d at 1316. It bears emphasis that “[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction.” *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (internal quotation marks omitted), *aff’d*, 481 F.3d 1371 (Fed. Cir. 2007).

In addition to the specification, a court “should also consider the patent’s prosecution history, if it is in evidence.” *Markman*, 52 F.3d at 980. The prosecution history, which is “intrinsic evidence,” “consists of the complete record of the proceedings before the PTO [Patent and Trademark Office] and includes the prior art cited during the examination of the patent.” *Phillips*, 415 F.3d at 1317. “[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.” *Id.*

A court also may rely on “extrinsic evidence,” which “consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” *Markman*, 52 F.3d at 980. For instance, technical dictionaries can assist the court in determining the meaning of a term to those of skill in the relevant art because such dictionaries “endeavor to collect the accepted meanings of terms used in various fields of science

and technology.” *Phillips*, 415 F.3d at 1318. In addition, expert testimony can be useful “to ensure that the court’s understanding of the technical aspects of the patent is consistent with that of a person of ordinary skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field.” *Id.* Nonetheless, courts must not lose sight of the fact that “expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence.” *Id.* Overall, while extrinsic evidence “may be useful” to the court, it is “less reliable” than intrinsic evidence, and its consideration “is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence.” *Id.* at 1318-19.

Finally, “[t]he construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be, in the end, the correct construction.” *Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that “a claim interpretation that would exclude the inventor’s device is rarely the correct interpretation.” *Osram GmbH v. Int’l Trade Comm’n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007). Thus, if possible, claims should be construed to uphold validity. *See In re Yamamoto*, 740 F.2d 1569, 1571 (Fed. Cir. 1984).

CONSTRUCTION OF THE DISPUTED TERMS

1. “proximal wall”

The parties first dispute the meaning of “proximal wall,” a term which appears in all three independent claims (claims 1, 9, and 20), as well as in dependent claims. While Braun’s proposed construction has evolved, Braun ultimately requested the construction “a wall on the

proximal side of the needle guard.” (Tr. at 11, 15)³ Terumo, by contrast, proposes that “proximal wall” be construed as “rear end wall closest to the user.” (D.I. 71 at 7)

Both parties agree that the dispute is essentially whether the claimed “proximal wall” may be any wall on the proximal side of the invention – that is, on the side closest to the medical practitioner who is inserting the IV – or whether it must instead be the wall closest to the user. Braun proposes the former, as its construction would permit the “proximal wall” to be “a wall towards the back.” (Tr. at 10) Terumo proposes the latter: “We say it’s the rear wall.” (*Id.* at 28) I recommend that the Court adopt Braun’s construction. Thus, I recommend that “proximal wall” be construed as “a wall on the proximal side of the needle guard.”

The claim language in which the disputed term appears neither supports nor detracts from either side’s proposed construction. That is, the claim language itself is consistent with the proximal wall being either a wall towards the back or being the rear wall. Claim 9, for instance, describes a proximal wall that has both a proximally facing and distally facing wall surface and two resilient arms extending distally of it. (‘613 patent, col. 16 lines 9-13) These limitations could be satisfied by either a wall close to the user or the wall closest to the user.

Turning next to the specification, I find strong support for Braun’s proposal. The specification repeatedly uses the term “proximal” as a relative term, to describe an area rather than a specific point within an area. For example, the specification refers to “a continuous, larger

³Braun earlier proposed that “proximal wall” be construed as “a structure on the proximal side of the needle guard that includes a proximally facing wall surface and a distally facing wall surface.” (D.I. 74 at 10) In this earlier Braun construction, the “proximal wall” could have been a structure such as a “proximal vertical arm” or a “vertical arm” or a “proximal arm.” (D.I. 74 at 12) At the hearing, Braun agreed that “‘proximal wall’ has to be a wall.” (Tr. at 11; *see also id.* at 15 (Braun acknowledging it would be willing to drop from its proposal the language following “that includes”).)

diameter proximal section 30.” (‘613 patent, col. 5 lines 27-28) Many other uses of “proximal” in the specification likewise relate to a direction or side. (*See, e.g., id.* col. 3 lines 44-45 (“further movement of the needle in the proximal direction”); *id.* col. 6 lines 1-2 (“guard . . . extends upward and proximally”); *id.* col. 6 lines 28-29 (“the needle moves proximally past the curved lip”); *id.* col. 6 lines 33-34 (“[a]s a result of needle 16 moving proximally past point C”); *id.* col. 6 lines 47-48 (“[i]f desired, a slot 60 may be formed in the needle shaft slightly proximal to the needle tip”); *id.* col. 6 lines 52-53 (“move the needle further in a rearward or proximal direction”); *id.* col. 6 lines 63-64 (“move the protected needle . . . in the rearward or proximal direction”); *id.* col. 6 line 66 (“prevent further proximal movement of the needle”); *id.* col. 7 line 39 (“front wall 82 extends in the proximal direction”); *id.* col. 8 lines 29-30 (“section 102 extends from section 98 in the proximal direction”); *id.* col. 8 lines 51-52 (“at a location proximal to point B”).)⁴

Terumo points out, correctly, that the claim term being construed is “proximal wall,” not “proximal.” Yet this does not change the fact that in the numerous instances cited above the specification uses “proximal” to describe something in a relative manner. Terumo identifies no instances in which the specification uses “proximal” to describe something as the “rearmost of its kind.”

⁴Other uses of the word “proximal” in the specification are ambiguous as to whether they are referring to relative areas or specific points. *See* ‘613 patent, col. 3 lines 5-6 (describing a catheter “having a proximal end and a distal end”); *id.* col. 3 lines 8-9 (“catheter hub is attached to the proximal end of the catheter”); *id.* col. 5 line 22 (“proximal end of a needle”); *id.* col. 5 lines 36-37 (“passageway 34 communicates at its proximal end”); *id.* col. 5 line 50 (“proximal end of the needle hub 12”). While these uses do not support Braun’s construction, neither do they support Terumo’s.

Terumo further argues that the specification uses “proximal wall” interchangeably with “rear wall” and “end wall,” such that the patentee explicitly defined “proximal wall” to be the “rear wall of the needle guard.” (D.I. 71 at 7-9) It is true that a patentee is free to be her own lexicographer and, when she is, her explicit definition will be adopted for purposes of claim construction. *See Phillips*, 415 F.3d at 1316. Here, however, I find no such express definition. The portions of the specification on which Terumo relies are, instead, descriptions of preferred embodiments of the invention depicted in the specification’s Figures 10A and 10B. This section of the specification begins by describing “[t]he embodiment of the spring clip needle guard 120 disclosed in FIGS. 10A [and] 10B.” (‘613 patent, col. 9 lines 28-29) One of the lines on which Terumo relies is from a description of the embodiment depicted in FIG. 10A. (‘613 patent, col. 9 lines 40, 48-49 (“As shown in FIG. 10A . . . [t]he proximal end of the needle 16 passes through the opening 134 in the rear wall 126.”)) The other line on which Terumo relies is from a description of the embodiment depicted in FIG. 10B. (‘613 patent, col. 10 lines 12, 17-21 (“As also shown in FIG. 10B . . . the crimp 138 on the needle shaft will come into contact with the end wall 126, and, since its width is greater than that of the opening 134, the end wall 126 will at this point prevent any further axial movement of the needle out of the needle guard.”)) It would be improper in the context of this patent to limit the broader claim language (“proximal wall”) to the particular preferred embodiment (“rear wall”) described in this portion of the specification, as nothing in either the claim language or specification calls for such a narrowing here. *See, e.g., Phillips*, 415 F.3d at 1323 (“[A]lthough the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments”); *Liebel-Flarsheim*, 358 F.3d at 908 (refusing to limit asserted claims to embodiments disclosed in the specification because the portions of the specification disclosing

those embodiments “do not expressly or by clear implication restrict the scope of the invention”).⁵

The pertinent prosecution history is not inconsistent with these conclusions. During prosecution of the patent-in-suit, certain claims were rejected in light of U.S. Patent No. 5,135,504 (hereinafter “the McLees Patent”). (D.I. 74 at 14; D.I. 85 Ex. B (2/6/06 Office Action at 4 (BBM-TER0000336)); D.I. 85 Ex. B (11/23/05 Appellant’s Brief at 5 (BBM-TER0000303))) The Patent Examiner viewed the McLees Patent as disclosing a proximal wall. But the patent applicant disagreed. (*See, e.g.*, D.I. 85 Ex. B (6/12/06 Amendment at 15 (BBMTER0000359) (applicant stating: “[t]he issue of whether McLees discloses a proximal wall was also discussed. While consensus was not reached, [the examiner] agree[d] that McLees does not disclose a proximal wall comprising both a proximally facing wall surface and a distally facing wall surface.”)); D.I. 85 Ex. B (11/23/05 Appellant’s Brief at 12) (BBM-TER0000310) (applicant stating: “In contrast, McLees discloses a hollow cylindrical tube that has a butt end but not a proximal wall. . . .”)). Subsequently, the applicant amended the claims to clarify that the claimed “proximal wall” in the patent-in-suit “comprises a proximally facing wall surface [and] a distally facing wall surface.” (D.I. 74 at 14; D.I. 85 Ex. B (6/12/06 Amendment at 8-11 (BBMTER0000352-55))) Thereafter, the Examiner allowed the claims to issue. (D.I. 85

⁵Terumo analogizes the instant patent to the one involved in *Honeywell Int’l, Inc. v. ITT Indus., Inc.*, 452 F.3d 1312, 1318 (Fed. Cir. 2006). There, the Federal Circuit concluded that the claim term “fuel injection system component” was properly limited to a “fuel filter,” in part because the written description “[o]n at least four occasions” referred to “the fuel filter as ‘this invention’ or ‘the present invention.’” *Id.* Here, Terumo identifies one place at which the Summary of the Invention states: “To these ends, the safety IV catheter of *the invention* includes a resilient spring clip needle guard that includes a distal or front end and a proximal or rear wall.” (‘613 patent, col. 2 lines 52-54) (emphasis added) In the context of the entire patent, I find that this reference to “the invention” is a description of a preferred embodiment.

Ex. B (2/7/07 Notice of Allowability at 2-3 (BBM-TER0000517-18) (“The subject matter not found was . . . the tip protector comprising a proximal wall having a proximally facing wall surface, a distally facing [w]all surface . . .”))) In light of the claim language and the specification, there is nothing in this prosecution history that would justify construing “proximal wall” in the manner Terumo requests.

Terumo also cites to a great deal of extrinsic evidence but it, too, does not support Terumo’s proposed construction. First, Terumo referred the Court to a dictionary definition of “proximal” (despite Terumo’s point that the term in dispute is “proximal wall” and not just “proximal”). Specifically, Terumo cited Webster’s Collegiate Dictionary, which defines “proximal” as “next to or nearest the point of attachment or origin.” (*See* D.I. 72 Ex. G at p. 949; Tr. at 31-32 (Terumo’s counsel discussing Terumo’s slides 11 and 22).) However, this is the second (of three) definitions of “proximal” given at that same page of that same dictionary. The first definition given is “situated close to: proximate.” (*See* D.I. 72 Ex. G at p.949.) Hence, the first-listed definition in the dictionary cited by Terumo appears to support Braun’s proposal, not Terumo’s.

Next, Terumo points to the 2001 deposition testimony of Mark Wynkoop, the ‘613 patent’s primary inventor, given in other litigation. (D.I. 97 at 6) According to Terumo, in this earlier deposition Wynkoop described the proximal wall as the “back wall,” the “[b]ackside of the clip,” and the part of the clip that “has to be there to hold everything together.” (D.I. 97 at 6) (quoting D.I. 98 Ex. 2 at p. 210) Then, in the instant case, in testimony given on December 30, 2009, Wynkoop again made clear – in Terumo’s estimation – that he thinks of wall 126 as the “back wall,” and that the back wall has to be there to “hold everything together.” (D.I. 97 at 6) (quoting D.I. 98 Ex. 1 at pp. 141-42, 157-58) However, as Braun correctly notes, Wynkoop’s

testimony in the cited portions of these depositions addresses either Braun's Introcan Safety® product, an embodiment of the '613 patent (*see* D.I. 140 Ex. A at pp. 209-10 (Wynkoop's 2001 deposition, answering "the scissor clip *on the Introcan Safety*, what's its function?") (emphasis added)) or relates to an embodiment disclosed in the '613 patent specification (*see* D.I. 140 Ex. B at pp. 137-42, 157-58 (Wynkoop, in his 2009 deposition, reiterating his 2001 testimony and adding that he calls 126 in Figure 10A the "back wall," but not opining as to meaning of "proximal wall" in the claims)). In neither instance does Wynkoop's testimony address the distinct issue of the breadth of the claimed "proximal wall" of the '613 patent.

Finally, Terumo argues that if the Court adopts Braun's construction of "proximal wall," then the disclosed invention would not work. (Tr. at 30-31, 35) This is because Braun's construction would permit more than one proximal wall, but, Terumo asserts, "[n]one of these designs work with multiple proximal walls." (Tr. at 35) Braun responds with the observation that, even under its construction of "proximal wall," "[t]here are all these other elements there as well that are required to make this thing function." (Tr. at 42) Therefore, according to Braun, the disclosed invention would work even if multiple proximal walls are permitted. I have been unable to find anything in the record that would support either of these attorney arguments. Therefore, I find no evidence on this point that persuades me the conclusion I reach above is incorrect.

Thus, again, I recommend that the Court construe the term "proximal wall" to mean "a wall on the proximal side of the needle guard."

2. "intersect"

Braun construes "intersect" to mean "to have one or more points in common from at least one perspective." (D.I. 74 at 16) Terumo construes the term to mean "to pierce or divide by

passing through or across, but not merely touching or overlapping.” (D.I. 71 at 14) I recommend adopting Braun’s proposed construction.

Both parties agree that the issue is whether “intersect” as used in the patent claims requires that items “pierce or divide” one another.⁶ Braun’s proposal would allow for items to “intersect” without piercing or dividing one another, provided that the items appear to have at least one point in common when looking at them from some perspective. (*See, e.g.*, D.I. 99 at 10 (Braun explaining its construction “capture[s] the requirement that two arms *appear* to have at least a common point, shown in the embodiments as crossing”) (emphasis added).) Terumo, by contrast, insists that items which “intersect” must pierce or divide one another.

The claim language refers to a “proximal wall” having “two arms that intersect one another and extend distally of the proximal wall in the ready to use position.” (‘613 patent, col. 16 lines 12-13) This claim language itself does not preclude either party’s proposed construction.

Turning to the specification, most relevant are Figures 10A and 10B, which depict a preferred embodiment. (‘613 patent at BBM-TER0000014) In this preferred embodiment, the arms (122 and 124 in Figure 10A) do not touch, pierce, or divide one another. (‘613 patent, col. 9 lines 28-34 & col. 10 lines 12-14) From the perspective depicted in Figures 10A and 10B, however, the two arms do appear to share a point in common (that is, the spot where the two arms appear to “cross” over one another). Thus, the embodiment disclosed at Figures 10A and

⁶It had previously appeared that the parties also disputed whether “intersect” as used in the patent claims requires that items touch one another. After the hearing, however, this issue no longer seems to be in dispute. (*See* Tr. at 64 (Braun stating it is prepared to accept a construction requiring touching, such as “to have one or more points in common from at least one perspective, but not merely touching”); Tr. at 62 (Terumo’s counsel not insisting on touching, stating “[t]hey don’t have to be touching”).

10B would be excluded from the claims if Terumo's construction were adopted. As a general matter, a claim interpretation that excludes a preferred embodiment is not a correct interpretation. *See generally Osram GmbH*, 505 F.3d at 1358 (“[A] claim interpretation that would exclude the inventor's device is rarely the correct interpretation.”). Such a result would be all the more anomalous here because, according to Terumo, this Figure 10 design “is the only version of the clip that worked.” (Tr. at 22-23; *see also* D.I. 97 at 12 n.8.)

Much attention has been devoted by the parties to the prosecution history of a patent related to the '613 patent-in-suit. The parties are in agreement that the prosecution history of a continuation-in-part patent is relevant. *See* Tr. at 49, 55; D.I. 71 at 19-20; D.I. 97 at 13; *see also Microsoft Corp. v. Multi-Tech Sys., Inc.*, 357 F.3d 1340, 1350 (Fed. Cir. 2004) (“Any statement of the patentee in the prosecution of a related application as to the scope of the invention would be relevant to claim construction, and the relevance of the statement made in this instance is enhanced by the fact that it was made in an official proceeding in which the patentee had every incentive to exercise care in characterizing the scope of its invention.”). Terumo finds within the file history of U.S. Patent Application No. 10/734,931 (the “'931 application”), which is a continuation-in-part of the '613 patent, a prosecution disclaimer.⁷ “Under the doctrine of prosecution disclaimer, a patentee may limit the meaning of a claim term by making a clear and unmistakable disavowal of scope during prosecution.” *Purdue Pharma L.P. v. Endo Pharms. Inc.*, 438 F.3d 1123, 1136 (Fed. Cir. 2006).

Terumo purports to find such a disclaimer in the patentees' efforts to distinguish two prior art references: U.S. Patent No. 4,929,241 (“Kulli”), and U.S. Patent No. 5,549,570

⁷The specifications of the '613 patent and the '931 patent application are essentially identical. (Tr. at 49, 55)

(“Rogalsky”). (D.I. 71 at 15; D.I. 72 Exs. N & O) In the course of persuading the Patent Examiner that Kulli and Rogalsky did not disclose intersecting arms, *see, e.g.*, D.I. 72 Ex. M (4/8/08 Office Action Summary at TMC0003576 (“Kulli in view of Purdy discloses the claimed invention except for the arms that ‘intersect.’”)), Braun made statements which, according to Terumo, require that “intersect” be construed to require piercing or dividing and further require excluding merely “overlapping” or “being biased against” one another.⁸ Thus, to Terumo, the

⁸The patentee statements on which Terumo relies are: (i) in an Appeal Brief, Braun wrote, “Nowhere in Rogalsky is there a teaching or suggestion of a needle protector clip having first and second resilient arms that intersect one another. Intersecting objects cut through or across one another.” (D.I. 72 Ex. P (8/26/08 Appellants’ Brief at TMC0003545)) Terumo characterizes this as “an affirmative definition of ‘intersect.’” (D.I. 71 at 16) Braun responds:

In particular, in response to the examiner’s contention that Rogalsky showed “an engagement and biasing of the two arms against each other” which, in the examiner’s view, taught arms that intersect (*Id.* at TMC0003576-77), Braun’s patent attorney showed this was incorrect. Rogalsky discloses the use of a “hood” 4, and Braun explained that in Rogalsky’s own depictions the “hoods” do not have any “portions that cut through or across another” like the intersecting arms in Braun’s patent application. (*Id.* at Ex. M at TMC0003576.) Instead, like Kulli, the portions identified as the alleged “arms” in Rogalsky only touch or overlap. Significantly, the statements describing the arms in the Braun application as “cutting through or across” each other are consistent with Braun’s proposed construction Cutting across defines the relative spatial relationship between the arms – it does not mean “piercing” or dividing.

(D.I. 99 at 11-12); (ii) in an Appeal Reply Brief, Braun told the PTO that intersect does not mean overlap. (D.I. 72 Ex. Q (3/2/09 Appellants’ Reply Brief at TMC0003510 (“Furthermore, the use of both ‘overlap’ and ‘intersects’ in the same claim implies that these two words have different scopes and meanings.”)) About this Braun says: “after the examiner changed position in response to Braun’s appeal brief and argued that, in his view, the Kulli reference did disclose ‘intersecting arms,’ Braun’s attorney explained that the examiner was correct in his original position. (D.I. 72, Ex. Q at TMC0003509.) Kulli does not disclose ‘intersecting arms’ because the arms only overlap – they do not share a common point.” (D.I. 99 at 12 (citing D.I. 72 Ex. N at TMC0001331-33)); and (iii) in its Appeal Brief, Braun told the PTO that intersect does not mean engaged and biased. (D.I. 72 Ex. P (8/26/08 Appellants’ Brief at TMC0003546) (“In Kulli, for example, the shields 24, 26 are engaged and biased against one another, but they do not intersect.”)) Braun answers that it “explained that the Rogalsky reference does not disclose ‘intersecting arms’ because they are merely ‘engaged and biased against each other.’ (D.I. 72,

construction Braun is proposing in the instant litigation would include arms that are merely touching, overlapping, or engaged and biased against each other, which are meanings of “intersect” that were all disclaimed by Braun during prosecution of the ‘931 application. (D.I. 71 at 17, 20; *see also* Tr. at 56 (“[T]he critical, critical thing to happen in the file history [is] . . . [t]hey told the patent examiner, intersecting objects cut through or across one another.”).)

Braun responds that Terumo’s purported prosecution “disclaimer” is “no disclaimer at all, but rather an attempt to distinguish the prior art in a manner consistent with Braun’s proposed construction.” (D.I. 99 at 10) Braun adds that the statements made during prosecution “were made to explain that the two cited prior art references did not teach or disclose ‘intersecting arms’ using the ordinary meaning of that term.” (D.I. 99 at 12) My review of the file history leads me to conclude that Braun is correct. I find no clear and unmistakable disavowal of the otherwise broad scope of the claim term “intersect.”

With respect to extrinsic evidence, both parties cite to dictionary definitions of “intersect.” Unsurprisingly, both parties have found dictionaries that support their own proposed

Ex. P at TMC0003546) That argument is not a ‘disclaimer’ of the meaning of ‘intersect.’ Rather, it points out that arms that only are biased against each other and do not cross or share a common point in a plane do not intersect.” (D.I. 99 at 12-13)

constructions.⁹ These are not particularly helpful and do not alter the conclusion I have reached above, on the basis of the intrinsic evidence.

3. “extending distally of,” “extend distally of”

Braun construes the terms “extending distally of” and “extend distally of” to mean “extends in a distal direction of.” (D.I. 74 at 18) As part of its proposed construction, Braun also requests that the Court state that this disputed claim term “[d]oes not require the referenced arm(s) to be directly attached to the proximal wall.” (*Id.*) Terumo takes the position that these terms require no construction beyond stating that the ordinary meaning applies. (D.I. 71 at 29) Further, Terumo argues “the claimed arms must be integral with or attached to the proximal wall based on the ordinary meaning of the claim as a whole (not just the phrase ‘extending distally of’).” (D.I. 155 at 1) I recommend largely adopting Braun’s proposed construction, with some modification.

The issue in dispute in connection with the “extend[ing] distally of” claim terms is whether the arms are required to be attached to the proximal wall. (Tr. at 80) Looking at the claims as a whole, Braun emphasizes the distinction between claims 1 and 9, on the one hand, and claim 20 on the other:

⁹Braun’s dictionary definitions are: “intersect” means “to have one or more points in common” and “intersection” means “point or line of contact between two lines.” (D.I. 74 at 16) (citing Webster’s Universal College Dictionary (2003) and Webster’s New International Concise Dictionary of the English Language (1997)) Terumo relies on Webster’s Ninth New Collegiate Dictionary (1991) (defining “intersect” as “to pierce or divide by passing through or across”); Webster’s Third New International Dictionary of the English Language Unabridged (1993) (defining “intersect” as “to pierce or divide by passing through or across”); Random House Webster’s College Dictionary (1995) (defining “intersect” as “to cut or divide by passing through or across”); and The American Heritage Dictionary (3d ed. 1993) (defining “intersect” as “to cut across or through”). (D.I. 71 at 15)

Claim 1: “and two resilient arms of different lengths extending distally of the proximal wall”

Claim 9: “two arms that intersect one another and extend distally of the proximal wall”

Claim 20: “at least one arm *attached to* and extending distally of the proximal wall” (emphasis added)

(‘613 patent, col. 15 lines 31-32; *id.* col. 16 lines 13-14, 59-60) (emphasis added) Only claim 20 expressly requires that an arm be “*attached to* and extending distally of the proximal wall” (emphasis added), suggesting that claims 1 and 9 do not contain the same requirement. (*See* D.I. 74 at 18-19; D.I. 160 at 2-4; Tr. at 68.)¹⁰

In opposing Braun’s construction, Terumo points out that every embodiment in the specification shows arms attached to the proximal wall. (D.I. 71 at 30) (referencing ‘613 patent at Figures 1-14) Braun does not disagree. (Tr. at 70) However, again, there is no basis here to limit the claims to the embodiments disclosed in the specification. *See, e.g., Kara Tech. Inc. v. Stamps.com Inc.*, 582 F.3d 1341, 1348 (Fed. Cir. 2009) (“The patentee is entitled to the full scope of his claims, and we will not limit him to his preferred embodiment or import a limitation from the specification into the claims.”); *see also Acumed LLC v. Stryker Corp.*, 483 F.3d 805, 805 (Fed. Cir. 2007).

Terumo’s principal argument against Braun’s proposed construction is that the issue of whether attachment is required is not a matter for claim construction but, rather, a question of infringement, which should not be resolved at this point in the case. (Tr. at 78-79; D.I. 71 at 30;

¹⁰As Terumo points out, claim 20 speaks of one arm “attached to” not “*directly* attached to.” (Tr. at 77) (emphasis added) I see no basis to recommend the phrase “direct” attachment, which would import additional ambiguity (for Braun does not explain the implicit distinction between “indirect” and “direct” attachment).

D.I. 155 at 1-2) I disagree. The parties have a fundamental dispute regarding the scope of these claim terms: whether or not they encompass products where the arms are not attached to a proximal wall. Braun says yes and Terumo says no. It is appropriate for the Court to resolve this dispute in connection with claim construction. *See O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008) (“[C]laim construction is a matter of resolution of disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the claims, for use in the determination of infringement. When the parties present a fundamental dispute regarding the scope of a claim term, it is the court’s duty to resolve it.”) (internal quotation marks and citation omitted).

Relatedly, nearly one month after the *Markman* hearing, Terumo offered a “compromise position,” stating that it “is willing to agree that the specific phrase ‘extending distally of,’ standing alone, does not require ‘direct attachment’ – so long as the record is clear that Terumo’s position is that the larger phrase ‘and two resilient arms of different lengths extending distally of the proximal wall’ does require the arms to be integral with or attached to the proximal wall.” (D.I. 155 at 1, 3)¹¹ As Braun notes, “Terumo’s new reliance on the ‘larger phrase’ in the claims

¹¹On March 5, 2010, nearly a month after the February 9, 2010 *Markman* hearing, Terumo filed an uninvited four-page single-spaced letter which “clarifies Terumo’s position regarding whether or not ‘direct attachment’ is required by the disputed term ‘extending distally of.’” (D.I. 155 at 1) During the hearing, Terumo’s counsel had expressly stated “[w]e have never said direct attachment is required. . . . We’re not going to get up and tell the jury direct attachment is required.” (D.I. 126 at 72) In the post-hearing letter, however, Terumo indicated it “wants to clarify that while it does not intend to argue the specific phrase ‘extending distally of’ requires ‘direct attachment,’ it does intend to argue that the claimed arms must be integral with or attached to the proximal wall based on the ordinary meaning of the claim as a whole (not just the phrase ‘extending distally of’).” (D.I. 155 at 1) The Court provided Braun an opportunity to respond to Terumo’s untimely post-hearing submission (which Terumo did not seek leave to file), and Braun did so on March 15, 2010. (D.I. 160) The Court also offered Braun the opportunity to file a motion seeking additional relief (D.I. 157), but Braun chose not to do so.

is a distinction without a difference.” (D.I. 160 at 2) The dispute as to whether the arms must be attached to the proximal wall remains. (*See, e.g.*, D.I. 155 at 2 (“Terumo believes the Court’s construction should make clear that the arms must be ‘integral with or attached to’ the proximal wall.”).) That dispute has been placed before the Court in the context of a dispute as to the proper construction of the “extending distally of” terms. Hence, again, I believe the Court should address that dispute now, in the course of construing the disputed claim terms.

Based on the foregoing analysis, I recommend that “extending distally of” and “extend distally of,” as those terms are used in claims 1 and 9, respectively, be construed as “extending [or extend] in a distal direction away from the proximal wall, without the necessity of being attached to the proximal wall.”¹²

**4. “arms of different lengths,” “arms have dissimilar lengths,”
and “the at least one and the second arm have dissimilar lengths””**

Braun construes the phrases “arms of different lengths,” “arms have dissimilar lengths,” and “the at least one and the second arm have dissimilar lengths” to mean “arms which have different ending points on the axial dimension.” (D.I. 74 at 19) Terumo instead believes these phrases should be given their ordinary and customary meaning and, therefore, has not provided any proposed construction. (D.I. 71 at 28) The issue is whether these “arms of different lengths” terms refer to ending points (Braun’s view) or instead refer to a measurement of distance from one end of the arms to the other (Terumo’s view). I believe they refer to ending points.

¹²The language I have recommended will, while remaining true to the claims and the specification, be easier for the jury to understand. “Extend[ing] of” is a grammatically awkward phrase. (*See* Tr. at 74.) While Braun has resisted “extend[ing] from” (even though it is less awkward), this resistance stems from Braun’s concern that “extend[ing] from” would require a “direct attachment” between the arms and the proximal wall. (*See* Tr. at 69-70.) The addition in the construed claim of the phrase “without the necessity of being attached to the proximal wall” addresses this concern.

Braun relies on the specification to support its construction. (D.I. 99 at 15) For example, the patent states: “the end walls 130 overlap one another at a location distally in front of the needle tip, thereby to form a barrier that prevents inadvertent contact with, and distal movement of, the needle tip.” (‘613 patent, col. 10 lines 6-9) Braun emphasizes that overlapping arm ends are necessary to block the needle tip, which is the essence of the invention. (*See, e.g.*, Tr. at 82 (“[T]he needle guard has to fit into a small catheter hub and the overlapping arms permit a double protection mechanism from the tip escaping within the small space.”); *id.* at 83 (“[I]f you didn’t have overlapping arm ends, the arms wouldn’t effectively block the needle tip.”); *id.* at 84 (“The purpose, the whole purpose behind having the arms of different lengths is the overlapping end.”).) As Braun further points out, “nowhere in the patent specification does the patent suggest measuring arm lengths or measuring lengths from Point A to Point B as the determination for meeting this claim term.” (Tr. at 83)

It is true, as Terumo has explained, that one can accomplish different ending points with arms of the same length. (D.I. 97 at 22-23) (“[A]t least in some embodiments, it *is* possible to use arms of the same length to achieve arms with different end points in the axial dimension. For example, if the proximal wall was angled (rather than being perfectly vertical), then two arms of the same length extending from the proximal wall would have different ending points in the axial dimension.”) Nothing about Braun’s proposed construction neglects this reality nor excludes such an embodiment from the scope of the patent claim. Indeed, at the hearing, Braun’s counsel conceded the basic geometric fact that arms having the same absolute length (i.e., distance from front to back) can still have different ending points and accomplish the purpose of the invention. (Tr. at 84) This demonstrates that the “arms of different lengths” terms in this patent are *not* being used in their ordinary meaning.

Therefore, I recommend that these terms be construed to mean “arms which have different ending points on the axial dimension.”

5. “crimp”

Braun construes “crimp” to mean “a portion of the needle which is sufficiently small to allow the needle to move axially along the catheter but which is greater in width than the opening.” (D.I. 74 at 21) Alternatively, Braun has no objection to defining the term “crimp” as a “bulged section” or “segment of increased width.” (D.I. 99 at 18) Terumo proposes that “crimp” should be given its ordinary and customary meaning and, therefore, has not provided a proposed construction. (D.I. 71 at 25) I recommend adopting Braun’s original construction.¹³

Braun’s proposed construction is derived from the specification’s description of a “crimp.” For example, the specification states: “The safety catheter illustrated in FIGS. 1C and 1D is the same as that illustrated in FIGS. 1A and 1B, except that the slot 60 in the needle shaft in the latter is replaced in the former by *a crimp 61 whose width is greater than that of the opening 58 in the vertical arm 54.*” (‘613 patent, col. 6 lines 58-62; *see also id.* col. 9 lines 18-22 (“The safety catheter illustrated in FIGS. 7D and 7E is the same [a]s that illustrated in FIGS. 7A and 7B, except that the slot 60 in the needle shaft in the latter is replaced in the former by *a crimp 61 whose width is greater than that of the opening 58 in the vertical arm 54.*”); *id.* col. 9 lines 49-53 (“The needle 16 includes a[] *crimp 138 which is sufficiently small to allow the needle 16 to move axially along the catheter 24 but is greater in width than the opening 134 . . .*”); *id.*

¹³Initially, the primary dispute between the parties was whether the “crimp” must be manufactured through a traditional crimping process. Terumo insisted it must be, while Braun disagreed. (D.I. 71 at 26 n.13; D.I. 74 at 23) At the hearing, Terumo stated that it is no longer requesting that the Court’s construction of “crimp” require that it be “something produced by crimping.” (Tr. at 99; *see also* D.I. 97 at 16-17.)

col. 11 lines 61-64 (“The needle 16 includes a[] *crimp 138 which is sufficiently small to allow the needle 16 to move axially along the catheter 24 but is greater in width than the opening 134 . . .*.”) (all emphasis added).)

Terumo asserts that the ordinary meaning of “crimp” is “a structure with inwardly extending depressions and corresponding outwardly extending bulges.” (D.I. 71 at 26 n.13) Braun does not disagree, but it contends that this type of “crimp” is only a preferred embodiment. On this point, Braun is correct. As the specification states:

[T]he crimp 138 formed in the needle 16 *preferably* defines a pair of generally opposed, inwardly extending depressions 138b, which are disposed generally orthogonally with respect to the bulges 138a. The bulges 138a define a crimp 138 having a width, dimension W, which is small enough to facilitate movement of the needle 16 within the catheter 24, as shown in FIG. 14, and which is too large to pass through the central opening 134 formed in the end wall 126 of the needle guard 120, as discussed above.

The crimp 138 may be formed by any contemporary crimping process, such as those processes wherein two jaws of a vise or crimper come together so as to squeeze the needle 16 in a manner which forms the depressions 138b of FIG. 19, thereby consequently also forming the bulges 138a.

(‘613 patent, col. 13 lines 9-19) (emphasis added) “[T]he use of the term ‘preferably’ makes clear that the language describes a preferred embodiment, not the invention as a whole.” *Cordis Corp. v. Medtronic AVE, Inc.*, 339 F.3d 1352, 1357 (Fed. Cir. 2003).

Terumo also points to the prosecution history, and complains that adopting Braun’s proposal will deprive Terumo of an inequitable conduct defense that may otherwise be meritorious. In addition to Braun’s invention disclosure documents, appearing to illustrate the

conception of a “crimp” as early as February 1998 (Tr. at 95-96, 107),¹⁴ the prosecution history reveals that the crimp (along with Figures 10A and 10B depicting it) has been in the specification since June 1998 – although the word “crimp” did not appear until August 2000, when “crimp” was substituted for the prior version’s “bulge” (Tr. at 94-95, 101).¹⁵ As Braun explained: “The originally filed applications depicted and described ‘crimps,’ albeit calling some of them bulges. The examiner permitted without objection the subsequent substitute specification substituting the term ‘crimp’ for ‘bulge’ in certain places to describe the identical subject matter.” (D.I. 74 at 23) Terumo’s argument about the impact Braun’s construction has on Terumo’s inequitable conduct

¹⁴With respect to invention disclosure, Braun illustrates with various documents that the inventors apparently conceived of a “crimp” as early as February 1998. *See, e.g.*, D.I. 99 at 17; D.I. 100 Exs. A, B & C). This was before filings within the ‘613 patent family tree such as U.S. Patent No. 6,117,108 (“the ‘108 patent”), filed in June 1998; U.S. Patent No. 6,287,278 (“the ‘278 patent”), filed in October 1998; and U.S. Patent No. 6,616,630 (“the ‘630 patent”), filed in August 2000. (Tr. at 94-95; D.I. 75 Exs. E & F) Also, Wynkoop testified that he and a co-inventor came up with the idea of putting a crimp on the needle sometime in 1998. (D.I. 140 Ex. B at 161)

¹⁵For example, in the ‘278 patent application, filed in October 1998, the preferred embodiment depicted in Figure 10A was described as “[t]he needle 16 includes an *increased diameter bulge 138*, which is sufficiently small to allow the needle 16 to move axially along the catheter 24, but greater in width than the opening 134.” (D.I. 75 Ex. E at FIG. 10A & col. 8 lines 44-48) (emphasis added) In connection with Figure 10B, the same ‘278 patent stated: “If an attempt is made . . . to pull the needle further to the right, as viewed in FIG. 10, out of the needle guard, the *bulge 138* on the needle shaft will come into contact with the end wall 126, and since its diameter is greater than that of opening 134, the end wall 126 will at this point prevent any further axial movement of the needle out of the needle guard.” (D.I. 75 Ex. E at FIG. 10B & col. 9 lines 9-15) (emphasis added) In the ‘630 patent, filed in August 2000, the same preferred embodiment was depicted in the same Figure 10A, but now it was described as: “[t]he needle 16 includes an *crimp 138* which is sufficiently small to allow the needle 16 to move axially along the catheter 24 but is greater in width than the opening 134.” (D.I. 75 Ex. F at BBM-TER0001289) (emphasis added) In connection with Figure 10B, the ‘630 patent stated: “If an attempt is made . . . to pull the needle further to the right, as shown in FIG. 10B, out of the needle guard, the *crimp 138* on the needle shaft will come into contact with the end wall 126, and, since its width is greater than the diameter of the opening 134, the end wall 126 will at this point prevent any further axial movement of the needle out of the needle guard.” (D.I. 75 Ex. F at BBM-TER0001290) (emphasis added)

defense – *see* Tr. at 100-01 (“If you go with their construction, these very legitimate defenses go away. Because if it’s just a bulge section, they’re able to say, well, that was in the patent from the beginning.”) – is not a persuasive basis for adopting Terumo’s construction.

Terumo also again relies on the deposition testimony of inventor Wynkoop. Again, however, this testimony is not much help to Terumo. In response to the question “do you think, for example, people in the shop, when someone says, ‘We need to crimp this,’ they know what that is?” Wynkoop replied, “In my shop? I would say most of them, yes.” (D.I. 140 Ex. B at 130-31) As an initial matter, in the deposition question the word “crimp” is used as a verb, while in the claims it is used as a noun. Second, even assuming that everyone in Wynkoop’s shop is a person having ordinary skill in the art, all that Wynkoop stated was that he would “think” (but is evidently not sure) that “most of them” (not all) would know what it means to crimp something. Finally, to the extent the Court must construe the claims in a manner that will help a jury to understand the meaning the claims have to one of ordinary skill in the art,¹⁶ Wynkoop’s testimony provides no basis for confidence that lay jurors would know (without construction) the ordinary meaning of a “crimp.” (*See generally* D.I. 140 Ex. B at 131 (Wynkoop explaining workers in his shop would understand “crimping” “[b]ecause of their mechanical ability and the things that we do in the shop”) (emphasis added).)

¹⁶*See generally* *Power-One, Inc. v. Artesyn Technologies, Inc.*, 599 F.3d 1343, 1348 (Fed. Cir. 2010) (“The [claim] terms, as construed by the court, must ensure that the jury fully understands the court’s claim construction rulings and what the patentee covered by the claims.”) (internal quotation marks omitted); *see also* D.I. 71 at 26 n.13 (Terumo inviting Court to consider if “it would assist the jury to provide a construction [of ‘crimp’] beyond the ordinary meaning”); *but see* *Riddell, Inc. v. Schutt Sports, Inc.*, 2009 WL 1444217, at *1 (W.D. Wis. May 21, 2009) (refusing to construe claim terms where the only proffered purpose of such a construction was that “construction of the limitations will assist the jury in its deliberations”).

Hence, I recommend that the Court construe “crimp” to mean “a portion of the needle which is sufficiently small to allow the needle to move axially along the catheter but which is greater in width than the opening.”

6. “arm”

Braun contends that “arm” is a readily understandable term that does not require construction. (D.I. 74 at 24) If, however, it is construed, Braun proposes “a structure that extends of another part of the structure.” (*Id.*) Terumo proposes that “arm” be construed as “a part of a structure, machine or an instrument projecting from a main part, axis, or fulcrum.” (D.I. 97 at 10 & 11 n.7; Tr. at 111, 122) I recommend adopting Braun’s proposed construction.

This conclusion essentially follows from my earlier recommendation that “extend[ing] distally of” be construed in a manner that does not require the arms to be attached to the proximal wall. I understand Terumo’s proposed construction of “arm,” and particularly the phrase “projecting from,” to require attachment between the arms and the proximal wall (or at least attachment of the arms to some other structure). For the same reasons I rejected the requirement of attachment in connection with the “extend[ing] distally of” terms, I again reject it here. Reading a limitation of attachment into the claims would not be consistent with the claim language and is not supported by the specification. *See generally Linear Tech. Corp. v. Int’l Trade Comm’n*, 566 F.3d 1049, 1055 (Fed. Cir. 2009) (holding where “nothing in the claim language or specification . . . support[ed] narrowly construing the terms,” terms would be “accorded their full scope”).

Both parties cite to numerous dictionary definitions to support their proposals. (D.I. 71 at 12; D.I. 74 at 24) I find these extrinsic sources unhelpful to determining the proper construction of “arm” in the patent-in-suit. The proper construction here is one that accurately accounts for

the context in which the claim term appears, in light of the entire patent, including all of the claims and the specification. Here, I conclude that the proper construction is the one proposed by Braun, which I recommend that the Court adopt.

7. “needle protector clip”

Braun construes “needle protector clip” to mean “needle guard.” (D.I. 99 at 20; Tr. at 115) Terumo instead construes the term to mean “unitary needle guard.” (D.I. 71 at 21) Thus, the only dispute is whether the word “unitary” should be part of the construction. (Tr. at 115)

There is not entire agreement as to what “unitary” means. To Terumo, “unitary” means made of a single piece of metal. (D.I. 71 at 23; Tr. at 129) Braun disagrees. (D.I. 99 at 21 n.5; Tr. at 116-17) For purposes of my analysis, I interpret “unitary” to mean “made of a single piece of metal.”

Nothing in the language of the asserted claim itself indicates a limitation that the needle protector clip (or needle guard) be unitary. Independent claim 9, in which the disputed term appears, reads in pertinent part:

a ***needle protector clip*** positioned in the clip cavity and having a ready to use position, in which the ***needle protector clip*** is positioned proximally of the needle tip, and a protective position, in which the ***needle protector clip*** blocks the needle tip

(‘613 patent, col. 16 lines 4-8) (emphasis added)

Terumo, as support for its “unitary” limitation, points out that the other two independent claims – claims 1 and 20, which each claim “a tip protector” – have dependent claims – claims 7 and 23, respectively – “*wherein the tip protector is an integrally formed unit*” (emphasis added). (See D.I. 71 at 22; ‘613 patent, col. 15 lines 60-61 & col. 17 lines 6-7.) To Terumo, it follows

that claim 9, which lacks a similar dependent claim, must somehow also be limited to an “integrally formed unit,” a phrase evidently having the same meaning as “unitary.” I do not agree. Rather, the structure of these claims indicates that the patentee knew how to limit his claims to “unitary” clips when he wished to do so, rendering it meaningful that he chose not to do so in claim 9.

Turning to the specification, it, like the claims themselves, demonstrates that the patentee knew how to indicate when an embodiment was “unitary.” Several embodiments are expressly described as a “*unitary* needle guard” or a “*unitary* spring clip.” (‘613 patent, col. 3 lines 13-14; *id.* col. 5 line 60) (emphasis added) Other embodiments, however, are not described as “unitary,” such as “the spring clip needle guard 96” shown in Figures 7A-7C and “the spring clip 96” shown in Figures 8 and 9. (‘613 patent, col. 8 lines 24-28)

Terumo offers several justifications for a “unitary” limitation, but none are persuasive. First, Terumo emphasizes the first sentence of the Abstract, which states: “[a] safety IV catheter includes a *unitary*, resilient needle guard received in a catheter hub.” (D.I. 71 at 22-23) But neither the Abstract nor any part of the specification states that “unitary” is an “essential component” of the invention; there is no basis to import this limitation into the claims. *See Saunders Grp. v. Comfortrac, Inc.*, 492 F.3d 1326, 1332-33 (Fed. Cir. 2007). Next, Terumo observes that the specification discloses that one of the objects of the invention is “to provide a safety IV catheter of the type described which is relatively simple and inexpensive to manufacture.” (‘613 patent, col. 2 lines 46-48) However, even assuming it is easier and cheaper to manufacture a unitary needle guard than one consisting of multiple pieces, there is no teaching in the patent that these features of the manufacturing process are essential to the invention. Nor is there any requirement that every claim of a patent accomplish every objective of the invention.

See generally i4i Ltd. P'shp v. Microsoft Corp., 598 F.3d 831, 843 (Fed. Cir. 2010) (“[N]ot every benefit flowing from an invention is a claim limitation.”). Finally, Terumo again cites to Wynkoop’s deposition, but again the testimony on which it relies does not address the scope of the claims. (D.I. 98 Ex. 1 at p. 140-41 (Wynkoop reiterating 2001 testimony about embodiment depicted in Figure 10A))

Thus, I recommend that the Court construe “needle protector clip” as a “needle guard.”

RECOMMENDED CONSTRUCTIONS

For the reasons set forth above, I recommend that the Court construe the disputed claim terms as follows:

1. The term “proximal wall” be construed as “a wall on the proximal side of the needle guard.”
2. The term “intersect” be construed as “to have one or more points in common from at least one perspective.”
3. The terms “extending distally of” and “extend distally of,” as used in claims 1 and 9, respectively, be construed as “extending [or extend] in a distal direction away from the proximal wall, without the necessity of being attached to the proximal wall.”
4. The terms “arms of different lengths,” “arms have dissimilar lengths,” and “the at least one and the second arm have dissimilar lengths” be construed as “arms which have different ending points on the axial dimension.”
5. The term “crimp” be construed as “a portion of the needle which is sufficiently small to allow the needle to move axially along the catheter but which is greater in width than the opening.”

6. The term “arm” be construed as “a structure that extends of another part of the structure.”


7. The term “needle protector clip” be construed as “needle guard.”

I further recommend that, as agreed upon by the parties, the Court construe the term “clip stopping section,” as used in claims 1-6 and 8, to mean “a section of the needle for stopping the clip, including but not limited to a crimp.”

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections **of no longer than ten (10) pages within fourteen (14) days after being served with a copy of this Report and Recommendation.** Fed. R. Civ. P. 72(b). The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the district court. *See Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987); *Sincavage v. Barnhart*, 171 Fed. Appx. 924, 925 n.1 (3d Cir. 2006). **A party responding to objections may do so within fourteen (14) days after being served with a copy of objections; such response shall not exceed ten (10) pages. No further briefing shall be permitted with respect to objections without leave of the Court.**

The parties are directed to the Court’s Standing Order In Non-*Pro Se* Matters For Objections Filed Under Fed. R. Civ. P. 72, dated November 16, 2009, a copy of which is available on the Court’s website, www.ded.uscourts.gov/StandingOrdersMain.htm.

Dated: June 3, 2010



Leonard P. Stark
UNITED STATES MAGISTRATE JUDGE